



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/701,303 11/28/00 SAND

A 0020-4771P

002292 HM22/0810
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER

JOYNES, R

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

BEST AVAILABLE COPY

Office Action Summary

Application No.

09/701,303

Applicant(s)

SANO ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2001 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statement filed on February 27, 2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujioka et al. (US 5011692, hereafter "Fujioka"). Fujioka teaches as pharmaceutical preparation capable of releasing active agents sustainedly and in a pulse-like manner (Col. 1, lines 6-8). The preparation has alternating layers in which one layer (A) comprises a drug and the second layer (B) contains no drug or a slight amount of the same or different drug (Col. 2, lines 31-41). The polymers that are used for the layers (A & B) include collagen, gelatin, polylactic acid, polyglycolic acid, poly(lactide-co-glycolide), silicone polymer, and polyvinyl acetate (Col. 2, line 57 – Col. 3, line 4). Each drug-containing layer comprises one or more drugs (Col. 4, lines 12-25). Alternatively, each layer contains a different drug (Col. 4, lines 12-25). The preparation also contains a polymeric coating (C) such as silicone polymers or polyvinyl acetate (Col. 3, lines 5-15). The drug of the preparation is released from a face that is not coated with the polymeric coating (C) (Col. 6, lines 48-50). Additionally, the preparation is formed in the shape of a cylinder, trigonal prism or tetragonal prism (Col. 7, lines 17-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (EP 0659406, hereafter "Sano") in view of Fujioka et al (US 5011692, hereafter "Fujioka"). Sano teaches a rod-like drug formulation comprising a non-disintegrating inner layer comprised of a biocompatible material that contains a uniformly dispersed water-soluble drug and outer layer comprised of biocompatible material wherein the outer layer surrounds the circumference of the inner layer (Page 3, line 56 – Page 4, line 5). The outer layer may be composed of silicones, polytetrafluoroethylenes, polyethylenes, polypropylenes, polyurethanes, polyacrylates or polymethacrylates (Page 5, lines 15-20). The inner layer may be the same as that of the outer layer or a biodegradable polymer (Page 5, lines 25-31). Preferably both layers are comprised of a silicone (Page 5, lines 18-20, 38-39). The inner layer may contain two or more layers containing different water-soluble drugs that may take the form of concentric circles with a single center of gravity (Page 6, lines 33-39). The preparation taught by Fujioka may in the shape of a circular cylinder, prism or elliptical cylinder (Page 6, lines 29-32). Additionally, the rod or cylinder is prepared such that the ends of the preparation are open to the surrounding environment (Page 7, lines 11-12).

Sano does not expressly teach that a non-degradable hydrophobic polymer material exists between the inner layer and the outer layer or between the multiple inner layers in which a water-soluble drug is dispersed.

The teachings of Fujioka are discussed above. Briefly, Fujioka teaches a multiple layer preparation in which one or more layers contain a water-soluble drug alternating with one or more layers that contain no drug, said preparation being coated with a polymeric coating.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a multiple layer pharmaceutical composition in the form of a rod or cylinder in which one or more layers contain a water-soluble drug wherein one or more alternating layers contain no drug or a slight amount of a drug, wherein the entire preparation is coated wherein an end or face of the preparation is exposed to the surrounding environment.

One of ordinary skill in the art would have been motivated to do this to prepare a pharmaceutical composition that releases one or more drugs in a sustained release or pulsatile fashion.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703)

Application/Control Number: 09/701,303
Art Unit: 1615

Page 5

308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
August 9, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

